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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,158	04/25/2001	Ellen M. Beasley	CL001229	4168

25748 7590 06/26/2002

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EXAMINER

HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/841,158

Applicant(s)

Beasley et al.

Examiner

Fozia Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 23, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s).
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-2, 20-21, drawn to an isolated peptide consisting of the amino acid sequence set forth in SEQ ID NO:3 or 4, classified in class 530, subclass 350.
 - II. Claim 3, drawn to an antibody which selectively binds to a polypeptide, classified in class 530, subclass 389.1.
 - III. Claims 4-5, 8-11, 22-23, drawn to an isolated nucleic acid molecule, a vector comprising said nucleic acid, a host cell comprising said nucleic acid molecule and a method of producing a polypeptide by culturing said host cell, classified in class 435, subclass 69.1.
 - IV. Claim 6, drawn to a gene chip comprising a nucleic acid molecule, classified in class 536, subclass 23.1.
 - V. Claim 7, drawn to a transgenic animal, classified in class 800, subclass 8.
 - VI. Claim 12, drawn to a method for detecting the presence of a polypeptide in a sample by contacting said sample with a compound which selectively binds to said polypeptide, classified in class 435, subclass 7.21.
 - VII. Claim 13, drawn to a method for detecting the presence of a nucleic acid molecule in a sample by contacting said sample with a nucleic acid probe or primer which selectively hybridizes to said nucleic acid molecule, classified in class 436, subclass 504.

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- VIII. Claims 14-16, drawn to a method for identifying a modulator of a peptide by contacting said peptide with an agent and determining if said agent modulates said peptide, classified in class 435, subclass 7.2.
- IX. Claims 17 and 18, drawn to a pharmaceutical composition comprising an agent which binds to a peptide and a method of treating a disease by administering said agent, class and subclass undeterminable
- X. Claim 19, drawn to a method for identifying a modulator of the expression of a peptide by contacting a cell expressing said peptide with an agent and determining if said agent modulates the expression of said peptide, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V, IX are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The nucleic acid of Group II can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The protein of Group I can be used other than to make the antibody of Group III, such as used as a probe, or used therapeutically or diagnostically (e.g. in screening). Although the antibody of Group III can be used to obtain the nucleic acid of Group II, it can also be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography) or it may be used therapeutically. The transgenic nonhuman mammal of Group V can be used to produce large quantities of the protein of interest, however, it is structurally and functionally

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different from the inventions of Groups I-IV and IX. The polynucleotide of Group II does not encode the pharmaceutical composition of Group XI.

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the peptide of Group I can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Inventions I and VI, VIII are related as product and processes of use. However, the inventions are distinct because the peptide of Group I as claimed can be used in materially different methods, such as it can be used therapeutically.

Inventions II and VII, X are related as product and processes of use. However, the inventions are distinct because nucleic acid of Group II as claimed can be used in materially different methods, such as it can be used therapeutically in gene therapy.

Inventions VI-VIII and X are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different goals. The methods are distinct because each assay is performed for divergent purposes.

Inventions I is unrelated to inventions VII and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or

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they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups VII, X neither use nor produce the peptide of group I.

Inventions II and IV, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups IV and VIII neither use nor produce the nucleic acid of Group II.

Inventions III-V and IX are unrelated to invention VI-VIII and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Group II, the gene chip of Group IV, the transgenic nonhuman of Group V or the pharmaceutical composition of Group IX are neither used nor produced in any of the methods of Groups VI-VIII and X.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Additional Restriction Requirement

2. The claims of Groups I and II, are drawn to a multitude of polypeptide sequences and multitude of nucleic acid molecules, respectively, (amino acid sequences of SEQ ID Nos:3* or 4, and nucleotide sequences comprising SEQ ID Nos:1 or 3). This constitutes a recitation of an implied,

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mis-joined Markush group that contain multiple, independent and distinct inventions. Each of the nucleic acids are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. 121.

In the event that Applicant elects the invention of Group I or Group II, Applicant is additionally required to elect a single amino acid sequence or a single nucleic acid sequence. This requirement is not to be considered as a requirement of an election of species, since each of the compounds recited in alternative from is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

* (Applicants' attention is drawn to the fact that SEQ ID NO:3 is recited as being both an amino acid sequence and a nucleotide sequence in claims 1-2, 4-5)

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursdays from 7:00AM to 4:30PM (Eastern time).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

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Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
18 June 2002


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
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